a terminal disclaimer, signed by a representative of Applicant's assignee, which disclaims the terminal part of any patent granted from the present application which would extend beyond the expiration date of the full statutory term of either of U.S. Patent Nos. 4,950,266 or 5,196,004. In view of these terminal disclaimers, it is respectfully submitted that the rejection of claims 44-59 under the doctrine of obviousness-type double patenting should be withdrawn.

At page three of the Office Action, the Examiner objected to the specification under 35 U.S.C. §112, ¶1 as not providing support for the claimed invention because it purportedly does not disclose the use of a liquid, or of irrigating or transmitting fluid to the surgical site. At page five of the action, the Examiner noted Applicant's arguments that the specification provides such support, but stated:

> The Examiner notes that the cited passage on page 15 is concerned with providing a fluid (no mention of a liquid is made) to the probe lens tip area. It is the examiner's perception that Applicant has not disclosed performing surgery on the probe lens tip area. Thus, this cannot be considered to be the surgical sight and the claim language is not supported by such a recitation. (emphasis in original).

To satisfy the written description requirement of 35 U.S.C. §112, ¶1, the claimed subject matter "need not be described identically or literally." Behr v. Talbott, 27 USPQ2d 1401, 1407 (BPAI 1992). Rather, Applicant's specification satisfies the written description requirement of §112, ¶1 with respect to the

pending claims so long as the description is sufficiently clear that persons skilled in the art would have recognized that Applicant had developed the invention defined by those claims. Id. at 1407.

In Fig. 5 of Applicant's specification, a laser catheter is illustrated that irrigates the surgical site with a solution that is passed through a lumen and exists at an orifice 32. More particularly, the specification states:

> The second lumen in catheter 30 is provided for transmission of a flushing fluid or to apply suction to the probe lens tip area to clear the area of blood during surgery. Solutions injected into the catheter through tube 29 pass through the lumen in catheter 30 and exit at the distal end via a small orifice 32.
>
> Probe tip 34 consists of a lens arrangement which forms the laser energy into a beam 36 which is used to perform the surgical operations. (specification page 15).

As set above, the Examiner, in concluding that the specification does not support Applicant's claims, noted that although the specification mentions the use of a fluid, it does not specifically mention a "liquid". However, the description of a "flushing fluid ... to clear the area of blood during surgery" and of "solutions injected into the catheter" clearly indicate that a liquid can be used to irrigate the surgical site. As shown from the enclosed copies of the relevant pages attached as Exhibit A, Webster's Ninth New Collegiate Dictionary (1985) defines "fluid", "flush" and "solution" as follows:

fluid — a substance (as a liquid or gas) tending to flow or conform to the outline of its container. (emphasis added).

flush — a sudden flow (as of water); *also*: a rinsing or cleaning with or as if with a flush of water.

solution — an act or the process by which a solid, liquid or gaseous substance is homogeneously mixed with a liquid or sometimes a gas or solid (emphasis added); or
a homogeneous mixture formed by this process; *ESP*: a single-phase liquid system. (emphasis added).

As seen from the foregoing, although the identical word "liquid" is not used in Applicant's specification, a fluid includes a liquid and the terms "flushing fluid" and "solutions" clearly would have been understood by those skilled in the art as demonstrating that Applicant contemplated that a liquid could be used to flush blood from the probe lens tip area during surgery. Furthermore, as set forth in Applicant's Amendment and Third Request For Interference filed January 17, 1994, the process of irrigating a surgical site with a liquid while ablating tissue was known in the art, as shown by U.S. Patents Nos. 4,448,188 (Loeb) and 4,732,448 (Goldenberg). This further indicates that one of ordinary skill in the art, reading Applicant's specification, would have understood that the disclosed flushing fluid or solution could be a liquid. Thus, Applicant's specification is sufficiently clear that persons skilled in the art would have recognized that Applicant had contemplated the use of a liquid as a flushing fluid, and therefore, satisfies the requirements of 35 U.S.C. §112, ¶1. Behr, 27 USPQ at 1407.

At page 5 of the Office Action, the Examiner further stated that the description of transmitting a flushing fluid or solution to the lens tip area does not support the claim limitation of irrigating the surgical site because surgery is not performed "on the probe lens tip area." Again, the Examiner has misapplied the standard under 35 U.S.C. §112, ¶1 by requiring Applicant's specification to match word-for-word the language of the claims. Behr, 27 USPQ at 1407.

Applicant's specification describes the flushing fluid as being transmitted "to the probe lens tip area to clear the area of blood during surgery". (Specification, page 15). As shown in Fig. 5, and described at page 15, the probe tip 34 "consists of a lens arrangement which forms the laser energy into a beam 36 which is used to perform the surgical operations." The specification further states that the use of the optical fiber is desirable when performing surgery within the body because it can be used to transmit the laser energy "to the surgical location" (page 1), and the fibers are described as transmitting the laser energy "to the surgical area" (page 14). Thus, one of ordinary skill in the art would have clearly understood that when performing surgery within the body, the probe lens tip 34 is disposed adjacent the surgical site so that the flushing fluid transmitted to the probe lens tip area is also necessarily transmitted to the surgical site. Thus, the specification is sufficiently clear so that persons skilled in the art would have recognized that Applicant's invention included a step of

transmitting a flushing fluid to the surgical site to clear blood from the area. Therefore, Applicant's specification complies with the requirements of 35 U.S.C. §112, ¶1, and the objection to the specification under §112 should be withdrawn. Behr, 27 USPQ at 1407.

At page 3 of the Examiner's Action, claims 47 and 48 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite since the Examiner stated that it is unclear what further method steps are intended to be claimed by the recited structure. In response, applicant has amended claim 44 to recite the step of "providing a fiber optic cable having a proximal end and a delivery end". Other amendments were made to claim 44 to accommodate the new step. Claims 47 and 48 were amended to recite the apparatus limitations as being included in the providing step of claim 44. It is submitted that these amendments have overcome the Examiner's 35 U.S.C. §112, second paragraph rejection of claims 47 and 48.

At page four of the Office Action, the Examiner rejected claims 44-59 under 35 U.S.C. §103 as being unpatentable over Malyshev in view of L'Esperance '541. The Examiner stated that Malyshev teaches a method of performing a surgical procedure by removing tissue with a wavelength in the claimed range, and that L'Esperance teaches the desirability of using an optical fiber to conduct radiation. The Examiner then concluded that it would have been obvious to one of ordinary skill in the art to employ an optical fiber in the Malyshev device to provide greater

flexibility in manipulation. The Examiner's rejection of claims 44-59 is respectfully traversed for the following reasons.

A translation of Malyshev has been prepared by Applicant and is being submitted herewith for the convenience of the Examiner (see Exhibit B). Malyshev is directed to a method of cutting biological tissue that includes the simultaneous use of two lasers operating at different wavelengths. A first laser operates completely outside of Applicant's claimed wavelength range (within a range of 0.6-1 microns), and a second operates within a broad range of 1.5-10.6 microns. (Translation, page 3). In a discussion of one specific example, Malyshev suggests wavelengths of 1.06 microns and 10.6 microns for the two lasers. (Translation, page 6).

The prior art of record provides no teaching or suggestion to combine the teachings of L'Esperance and Malyshev to arrive at a system employing a fiber optic cable with a laser operating within a wavelength range of 0.6-1.0 microns or 1.5-10.6 microns, and in fact, teaches away from such a combination. Malyshev suggests a CO_2 laser operating at 10.6 microns, and Malyshev specifically discloses a delivery system which is not a fiber optic. Malyshev contains no suggestion to use a fiber optic delivery system. L'Esperance also discloses an embodiment wherein a CO_2 laser operating at 10.6 microns is employed, but without a fiber optic delivery system. At col. 4, lines 2-4, L'Esperance specifically states that when a fiber optic delivery system is employed, some laser type <u>other</u> than carbon dioxide

should be used, such as Argon, because laser energy at 10.6 microns could not be successfully delivered through any known fiber optic cable. Argon lasers, as shown in Fig. 1 of Applicant's specification, produce radiation at wavelengths of approximately .2 microns, well outside either range that Malyshev teaches is desirable. Thus, the prior art of record teaches away from combining a fiber optic cable with a laser operating within the wavelength range taught by Malyshev. Therefore, the Examiner's combination of Malyshev and L'Esperance results from an improper hindsight reconstruction of Applicant's invention, and the rejection of claims 44-59 under 35 U.S.C. §103 in view of the combination of these references should be withdrawn.

Furthermore, even if the teachings of Malyshev and L'Esperance are combined, the combination does not enable Applicant's claimed invention. Malyshev does not teach a laser operating over Applicant's full range of 1.4-2.2 microns because no teaching is provided to employ the lower end of Applicant's claimed range between 1.4 and 1.5 microns. Malyshev specifically omits wavelengths in the range of from 1.4 to 1.5 microns from those he suggests. Thus, the combination of Malyshev and L'Esperance does not teach or suggest Applicant's entire wavelength range.

More significantly, although Malyshev discloses a broad wavelength range that includes much of Applicant's claimed range, Applicant's range is a patentable species of the much broader range disclosed by Malyshev, because the claimed range is a

critical portion of the broader range. See, e.g., In re Waymouth and Koury, 182 USPQ 290, 293 (CCPA 1974). In Waymouth, the appellant sought claims to a device having an arc tube with a ratio of halogen atoms to mercury atoms between 0.08 and 0.75. Id. at 291, n. 1. A prior art patent to Reiling inherently disclosed a much broader ratio of from 0.0000001 to 1.3 Id. at 292. The Appellant demonstrated that his claimed range was critical in that it achieved unexpected results in comparison to the broader disclosure of the prior art. Id. at 293. Thus, the court found Appellant's claimed range to be patentable, despite the fact that it was a subset of the broader range disclosed by the prior art, stating:

> Although Reiling's range of possible ratios envelops the range claimed by appellants, we believe that the appellants' graph in Figure 2 demonstrates the necessary unexpected results. Those results follow from the selection of appellants' critical range, which is narrower than the extremely broad inherently disclosed range of Reiling. Id. at 293.

As set forth in the specification, Applicant's claimed wavelength range was selected because of its critical performance characteristics. In particular, Applicant was the first to identify the claimed range as being one that combined the attributes of being highly absorbed in water, having absorption lengths that were of about the correct distances for tissue removal, minimizing scattering, and being able to be transmitted down an existing fiber optic cable. (See Declaration Under 37 C.F.R. §1.132 of Edward L. Sinofsky dated 7/1/86, par. 8, attached hereto as Exhibit C).

The broad teaching in Malyshev is to use any wavelength within ranges of 0.6 to 1.0 microns and 1.5-10.6 microns. This teaching does not suggest the desirability of Applicant's range. Moreover, this teaching is plainly wrong, as applied to a fiber optic delivery system, since Malyshev's ranges include a number of wavelengths that would be totally unsuitable to remove tissue using a fiber optic. For example, radiation from a carbon dioxide laser operating a 10.6 microns was not, at the time of Applicant's invention, capable of being transmitted down a known fiber optic cable. See e.g., L'Esperance at col. 4, lines 2-4, wherein it is stated that when a fiber optic cable is used in the L'Esperance system, some laser types other than carbon dioxide should be used. In fact, all wavelengths from about 2.2 to 10.6 microns, at the time of Applicant's invention, were incapable of being transmitted down a fiber optic and thus they were totally unsuitable for such tissue removal. (See Declaration Under 37 CFR §1.132 of Edward L. Sinofsky dated 8/30/89, pars. 7-12, attached hereto as Exhibit D; See also Exhibit C, par. 8). Furthermore, for lasers operating at .6 microns or at wavelengths near .6 microns, almost no absorption of radiation occurs in tissue and this wavelength is the least suitable of all wavelengths for tissue removal. (Exhibit C, par. 12).

Therefore, Malyshev provides no suggestion to employ Applicant's claimed range, since the claimed range constitutes only a very small percentage of the wavelengths that Malyshev

teaches are desirable, and since the majority of Malyshev's wavelengths would be totally unsuitable for tissue removal using a fiber optic. The unexpected and superior results achieved by Applicant's claimed range, including the removal of tissue in desirable thicknesses with no thermal damage or carbonization (See Declaration Under 37 CFR §1.132 of Edward L. Sinofsky dated 2/1/89, par. 30, attached hereto as Exhibit E; See also Exhibit C, pars. 4-7) demonstrate the criticality of Applicant's claimed wavelength range, and render it patentable over the broad disclosure of Malyshev. Waymouth, 182 USPQ at 293.

Secondary considerations of nonobviousness further demonstrate the patentability of Applicant's claimed invention. See e.g., Truswal Systems Corp. v. Hydro-air Engineering, Inc., 2 USPQ2d 1034, 1038 (Fed. Cir. 1987); Stratoflex, Inc. v. Aeroquip Corp., 218 USPQ 871, 879 (Fed. Cir. 1983). At the time Applicant conceived his invention, no laser system existed that was suitable for removal of tissue deep within the body, even though the desirability of such a system was recognized in the published literature, including some of the literature cited in this application or its predecessors (See pars. 7-9 of Exhibit E; See pars. 4-6 of Exhibit D). Such recognition of a long-standing need or problem is objective evidence of the nonobviousness of Applicant's invention. See, e.g., Kalman v. Kimberly-Clark Corp., 218 USPQ 781, 791 (Fed. Cir. 1983); Northern Telecom, Inc. v. Datapoint Corp., 15 USPQ2d 1321, 1323-1324 (Fed. Cir. 1990).

Since the filing of Applicant's application and the publication of various articles and foreign applications describing Applicant's discovery, many other researchers have begun promoting and using lasers operating within the claimed wavelength range, thus confirming Applicant's discovery. (See par. 26 and par. 27 of Exhibit E). In fact, experimental confirmation of the criticality of the upper end of this claimed range of wavelengths has been reported subsequently by others who found that radiation from an Er:YAG laser operating at 2.9 microns was not suitable for tissue removal within the body because of the lack of an acceptable delivery system (See par. 25 of Exhibit E).

In view of the foregoing, Applicant's claims are patentable over the prior art, and are otherwise in condition for allowance and declaration of the requested interference with the Boutacoff patents.

At page four of the Office Action, the Examiner stated that the requested interference has not been declared for the further reason that Applicant's claims purportedly do not define the same patentable invention as Boutacoff's. The Examiner concedes that every limitation of the Boutacoff claims need not be supported by Applicant's specification, but states:

> However, the patentable limitations therein must be supported by the specification. The instant disclosure and claims to (sic, do) not support the patentable limitation of an endoscopic or arthroscopic procedure and the

> claims cannot constitute an interference count. (emphasis in original) (Office Action, page 5).

Initially, it is noted that claim 7 of the '354 Boutacoff patent is not so limited. The preamble of claim 7 recites: "A method of performing a surgical procedure...". This limitation is clearly patentably indistinct from the preamble of Applicant's claims herein. Thus, this basis for not declaring the interference is obviously inapplicable to claim 7 of the '354 patent.

Furthermore, applicant's specification is not in any way required to support Boutacoff's claims. See e.g., Heymes v. Takaya, 6 USPQ2d 2055, 2056 (BPAI 1988). Rather, to warrant declaration of the requested interference, Applicant need only show that his claims define the same patentable invention as Boutacoff's. Thus, the Examiner's statement is not technically correct, and Applicant assumes that it is intended to indicate that it is the Examiner's position that the preamble recitations of the Boutacoff claims of either an endoscopic or arthroscopic procedure render those claims separately patentable from the subject matter of Applicant's claims.

Even assuming that the foregoing is the Examiner's position, the Examiner is still incorrect. The preamble recitation in the Boutacoff claims of the method being used for an arthroscopic or endoscopic procedure is merely a statement of intended use that is not necessary to breath life into the claims. Therefore,

these recitations should not be given patentable weight, and they do not render the Boutacoff claims separately patentable over the subject matter of Applicant's claims. DeGeorge v. Bernier, 226 USPQ 758, 761, n. 3 (Fed. Cir. 1985) ("Generally, and in this case, the preamble does not limit the claims."). In this regard, Applicant notes that Boutacoff was required to terminally disclaim a portion of his second patent because the claims of the Boutacoff patents were determined not to be separately patentable, despite the fact that some claims are directed to an arthroscopic procedure and others to an endoscopic procedure and others to a surgical procedure generally without regard to the specific procedure performed (claim 7 of the '354 patent).

In addition, even if the recitations of the arthroscopic and endoscopic procedures were treated as limitations in the Boutacoff claims, those limitations would not render the Boutacoff claims patentable over Applicant's claims. Under the standard set forth in 37 C.F.R. §1.601(n), the claims of the Boutacoff patent define the same patentable invention as those of the present application if they recite subject matter which is the same as (35 U.S.C. §102) or obvious in view of (35 U.S.C. §103) the subject matter of Applicant's claims. As seen from the background section of the Boutacoff patents, prior to his invention those skilled in the art had been attempting to perform arthroscopic surgery with a laser coupled through a fiber optic cable:

> Experiments have been performed to show that a Nd:YAG laser can be coupled through a fiber optic cable to perform laser surgery on a meniscus. (col. 2, lines 2-4)
>
> Similarly, Nd:YAG lasers have been tried to perform arthroscopic meniscectomies ... (col. 2, lines 23-24).

Although Boutacoff states that prior art attempts to employ a laser and fiber optic to perform arthroscopic surgery had been largely unsuccessful, he states that this was so simply because no one had yet discovered a wavelength at which sufficient laser energy could be transferred down a fiber optic. This discovery falls squarely within the subject matter of Applicant's claimed invention. The prior art attempts at laser arthroscopic surgery with a fiber optic provide a clear teaching to employ the subject matter of Applicant's invention to perform arthroscopic or endoscopic surgery. If the subject matter of Applicant's claims was prior art to Boutacoff, Boutacoff's claims would clearly be unpatentable under §103. Thus, the Boutacoff claims define the same patentable invention as Applicant's.

At page five of the Office Action, the Examiner states that Applicant's argument that the steps of irrigating while ablating and maintaining a fluid field also fail to "render the Boutacoff claims patentable" is not convincing. This statement evidences a misunderstanding of Applicant's argument. Applicant has not argued that Boutacoff's claims are unpatentable over the prior art. Rather, Applicant has merely asserted that the steps of irrigating while ablating and maintaining a fluid field do not

render the Boutacoff claims separately patentable from Applicant's; i.e., Applicant asserts that Boutacoff's and Applicant's claims define the same patentable invention.

Furthermore, the Examiner references the file history of Boutacoff and states that the irrigating step was a necessary part of the claimed combination that gained allowance of the Boutacoff claims. The Examiner then asserts that "since the irrigating language is necessary to render the claim allowable, claims not including this step cannot be considered to define the same patentable invention as the claims of Boutacoff".

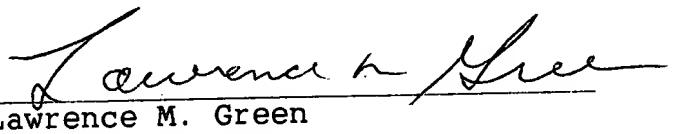
The Examiner's reliance upon the reasons for allowance of the Boutacoff claims is misplaced. Again, the key issue presented here is not whether the Boutacoff claims are patentable, but rather whether they define a separate patentable invention from Applicant's claims. The steps of irrigating while ablating or maintaining a fluid field that the Examiner asserts render Boutacoff's claims separately patentable over Applicant's are taught specifically in U.S. patents nos. 4,448,188 (Loeb) and 4,732,448 (Goldenberg), each of which is prior art to the Boutacoff patents. Copies of the Loeb and Goldenberg patents were included with Applicant's Amendment and Third Request For Interference, filed January 17, 1994. Neither the Loeb, Goldenberg, nor any other patent teaching the step of irrigating while ablating was of record during the prosecution of the Boutacoff patents. Thus, the Examiner's reliance on the fact

that the inclusion of these limitations was helpful in gaining allowance of the Boutacoff claims is misplaced, because the Boutacoff Examiner was not made aware that these steps were known in the art. In view of the clear teachings of the prior art Loeb and Goldenberg patents to perform the step of irrigation during ablation, the Boutacoff claims do not define a separately patentable invention from Applicant's.

In view of the above showing that Applicant's claims 44-59 are patentable to Applicant and define the same patentable invention as the claims of the Boutacoff patents, an interference should be declared. See MPEP 2307.02. Thus, it is respectfully requested that an interference be declared between this application and both Boutacoff patents, based on either of Applicant's proposed counts.

Respectfully submitted,

EDWARD L. SINOFSKY



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